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| 09/643,277      | 08/22/2000  | M. Bud Nelson        | B-28                | 8660             |

21130 7590 08/26/2002

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| EXAMINER |
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SAUNDERS, DAVID A

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| ART UNIT | PAPER NUMBER |
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1644

DATE MAILED: 08/26/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

643,277

Applicant(s)

NELSON et al

Examiner

D. SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 4/15/02
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-45 is/are pending in the application.
- Of the above claim(s) 1-9, 18-19, 29-30, 41-45 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 10-17, 20-28, 31-40, is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Pri rity under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

Office Action Summary

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The claims pending are 1-45.

Applicant's election with traverse of Group II (claims 10-17, 20-28 and 31-40) in Paper No. 5 (filed 4/15/02) is acknowledged. The traversal is on the ground(s) that no undue burden would be required to search for the additional invention and species. This is not found persuasive because the search for the kits of Group I would be more extensive, because the components of the kits could be used to test for conditions other than MS (e.g. for immune complexes of shed tumor antigens in cancer patients). The search areas and terms for the method Group I (removing sialo complexes) would be completely different from that for the assay. The search for the sialo complexes of Group IV would require a search of extensive prior art unrelated to MS (e.g. sialo complexes exist in cancer patients). The examiner does not even know what the "indicators" of Group III are (see 112, second infra) and cannot comment except that these appear to be in a different statutory class (or even a nonstatutory class) from the method and searches for these would be more extensive.

The requirement is still deemed proper and is therefore made FINAL.

Among the claims of Group II, claims 10-15, 17, 20-26, 28, 31-38 and 39-40 read on the elected species.

The drawings of 8/22/00 have been approved by the draftsman.

The disclosure is objected to because of the following informalities: at page 17 there is an extraneous dashed line.

Appropriate correction is required.

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At page 18, the current status of the referenced copending application must be updated.

Claims 10-17, 20-28 and 31-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10 and 20 are confusing as to what the recited "marker" is. It is not clear if the marker, which is determined by measuring the amount of the detection reagent, is present in complexes (of the two binding partners for the two affinity ligands employed in step (a) or is simply the binding partner of the affinity ligand that comprises a detection reagent. Note that claims 10 and 20 fail to state any function of the affinity ligand having no detection reagent in steps (b) or (c).

In like manner claim 31 fails to state, in step (b), how the antibody which does not comprise a detection reagent (added in step (a) is involved in determining the amount of the sialocomplexes.

In claims 10, 20, and 32 the term "indicator" is unclear. For example, is this the same as the "marker" (complexes present in the sample); is this a detectable entity (such as a colored solution in a test well) generated when measuring the amount of detection reagent; or is this a non-physical entity (such as a numerical value obtained by subtraction to obtain the difference in the value of the marker in the sample and the reference value)?

Several of the specification pages recite "the markers comprise indicators." (e.g. pages 16 and 19-21). These teachings would suggest the first of the above noted possible interpretations

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of the word "indicator" is correct. If so use of both the word "marker" and "indicator" is confusing, and applicant must use one term consistently.

Non-elected claims 18-19 and 29-30 refer to "indicator(s) generated from the method according to...". This would suggest that the second of the above interpretations of the word "indicator" is intended.

Claims 10, 20 and 32 themselves and the specification Examples would suggest that the "indicator" is some sort of numerical value. This would be consistent with the third of the above interpretations of the word "indicator". If this is intended, the claim must be further clarified as to how this indicator value is obtained. For example "difference" implies a subtraction, while "comparing" implies a division to obtain a quotient.

Clarification of the claims and an explanation of what is intended is required.

The following references are cited as of interest.

Hakamori et al., Kannagi et al., and Yamashima show various monoclonal antibodies directed against carbohydrate epitopes containing an alpha 2, 6 linked sialyl moiety. None of these references teaches detection of the target antigen in an immune complex or a sialoadhesin complex. Shimada et al. show an antibody to BD1a (TABLE 3 shows this does not have terminal 2-6 linkages). They measure GD1a in immune complexes by an assay format that substantially differs from that instantly.

Collins shows a sandwich assay for measuring a complex of an antigen and a host (patient) antibody thereto. Collins does not teach measuring such a complex in MS patients.

*find collins  
where is it?*

*check this  
again*

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Claims 10-17, 20-28 and 31-40 are allowable over the prior art of record, given the definition of the term "sialocomplexes" at specification page 6.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christian Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. Saunders:jmr

August 8, 2002

  
DAVID SAUNDERS  
PRIMARY EXAMINER  
ART UNIT 182 1644